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Smith & Nephew, Inc.
Summary of Safety and Effectiveness
TRIGEN® Low Profile Bone Screw

Contact Person and Address
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Date of Summary: 04/12/2011

Name of Device: TRIGEN® Low Profile Bone Screw
Common Name: Bone Screw
Device Classification Name and Reference: 21 CFR 888.3020 Intramedullary Fixation Rod
Device Class: II
Panel Code: Orthopaedics/87 HSB

Device Description
Subject of this Traditional 510(k) Premarket Notification is the TRIGEN® Low Profile Bone Screw. The subject device is a modification of the bone screws included in the (TRIGEN®) Titanium Intramedullary (IM) Nail System cleared by premarket notification K981529. The TRIGEN® Low Profile Bone Screw is manufactured from titanium alloy (Ti-6Al-4V), contains an internal hex drive feature in the screw head, and is available in the sizes included in Table 1 below.

Table 1: TRIGEN® Low Profile Screw Sizes

Diameter	Length Range
4.5 mm	20 mm – 65 mm, 2.5 mm increments
5.0 mm	20 mm – 80 mm, 2.5 mm increments 80 mm – 110 mm, 5.0 mm increments

The subject device is designed to be used with the SURESHOT® TAN Nails cleared under K092748 as well as TRIGEN® titanium intramedullary nail systems designed to use 4.5 mm or 5.0 mm diameter screws.

Intended Use
The TRIGEN® Low Profile Bone Screw can be used with several types of nails in Smith & Nephew's (TRIGEN®) Titanium Nail System. The TRIGEN® Low Profile Bone Screw therefore has the following indications:

Indications for interlocking intramedullary nails include simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of the long bones being treated.

In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability (e.g. Femoral

Antegrade Nail, Trochanteric Antegrade Nail and Femoral/Recon Antegrade Nail) are indicated for the following: subtrochanteric fractures, intertrochanteric fractures, and ipsilateral femoral shaft/neck fractures.

In addition to the indications for interlocking intramedullary nails, devices that use a retrograde femoral surgical approach (e.g. Knee Nail, Retrograde and Supracondylar Nails) are indicated for the following: comminuted supracondylar fractures with or without intra-articular extension; fractures that require opening the knee joint to stabilize the femoral condylar segment; fractures above total knee implants (peri-prosthetic fractures).

The TRIGEN® InterTAN nails are indicated for fractures of the femur including: simple shaft fractures, comminuted shaft fractures, spiral shaft fractures, long oblique shaft fractures and segmental shaft fractures; subtrochanteric fractures; intertrochanteric fractures; ipsilateral femoral shaft/neck fractures; intracapsular fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; bone lengthening and shortening.

SURESHOT® TAN Nails are indicated for fractures of the femur including simple long bone fractures, severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening; and for fixation of fractures that occur in and between the *proximal third* and *distal fourth* of the femur.

In addition, SURESHOT® TAN Nails contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability and are indicated for the following: subtrochanteric fractures; intertrochanteric fractures; ipsilateral femoral shaft/neck fractures; and intracapsular fractures.

The TRIGEN® Low Profile Bone Screw is intended for single use only.

Performance Data

Performance testing has been conducted to ensure the safety and effectiveness of the subject device. Static Torsional Strength, Bending Fatigue, and Axial Pullout Strength of the subject device have been evaluated. A review of the testing has demonstrated that there are no new issues related to the safety or effectiveness of the subject device.

Clinical data was not needed to support the safety and effectiveness of the subject device.

Substantial Equivalence Information

The overall design, indications for use, intended use, materials, and sterilization of the TRIGEN® Low Profile Bone Screw is substantially equivalent to the bone screws included in the (TRIGEN®) Titanium IM Nail System cleared under premarket notification K981529. The indications and intended use of the subject device is also similar to the bone screws included in the (Russell-Taylor®) IM Nail System cleared via K983942. Design features of the TRIGEN® Low Profile Bone Screw have been compared to the previously cleared devices in Table 2 below.

Table 2: Comparison of the TRIGEN® Low Profile Bone Screw to Predicate Devices

Device Comparison	TRIGEN® Low Profile Bone Screw (Subject Device)	(TriGen®) Titanium Nail System (K981529)	(Russell –Taylor®) IM Nail System (K983942)
Material	Ti-6Al-4V	Ti-6Al-4V	Stainless Steel
Diameter	4.5 mm and 5.0 mm	4.5 mm and 5.0 mm	4.5 mm and 5.0 mm
Length			
4.5 mm Diameter	20 - 65 mm, 2.5 mm increments	20 - 65 mm, 5.0 mm increments	20 - 65 mm, 5.0 mm increments
5.0 mm Diameter	20 - 80 mm, 2.5 mm increments; 80 - 110 mm, 5.0 mm increments	20 - 110 mm, 5.0 mm increments	25 - 90 mm, 5.0 mm increments
Head Drive	Internal Hex	External Hex	Internal Hex
Similar Thread Form	Y	Y	Y
Similar Cutting Tip Geometry	Y	N	Y

Conclusion

As previously noted, this premarket notification is being submitted to request clearance for the TRIGEN® Low Profile Bone Screw. Based on the similarities to the predicate devices and a review of the testing, the device is substantially equivalent to the bone screws currently marketed under premarket notifications K981529 and K983942.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
% Natalie P. Williams
Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, TN 38016

Re: K111025
Trade/Device Name: TRIGEN Low Profile Bone Screw
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: April 12, 2011
Received: April 13, 2011

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Dear Ms. Williams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

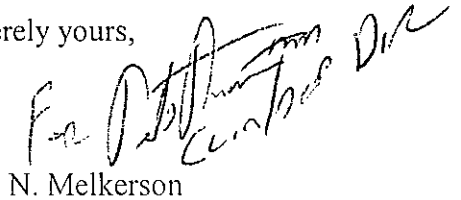
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111025 (pg 1/2)

Device Name: TRIGEN® Low Profile Bone Screw

Indications for Use:

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In addition to the indications for interlocking intramedullary nails, devices that contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability (e.g. Femoral Antegrade Nail, Trochanteric Antegrade Nail and Femoral/Recon Antegrade Nail) are indicated for the following: subtrochanteric fractures, intertrochanteric fractures, and ipsilateral femoral shaft/neck fractures.

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SURESHOT® TAN Nails are indicated for fractures of the femur including simple long bone fractures, severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening; and for fixation of fractures that occur in and between the *proximal third* and *distal fourth* of the femur.

In addition, SURESHOT®TAN Nails contain holes/slots proximally to accept screws that thread into the femoral head for compression and rotational stability and are indicated for the following:

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Indications for Use

subtrochanteric fractures; intertrochanteric fractures; ipsilateral femoral shaft/neck fractures; and intracapsular fractures.

The TRIGEN® Low Profile Bone Screw is intended for single use only.

Prescription Use (Part 21 CFR 801 Subpart D) X AND/OR Over-The-Counter Use (21 CFR 807 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111025